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(58) Field of Search

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Online: WPI, EPODOC, JAPIO

(54) Abstract Title

Method of selecting orthotics elements to correct pathological foot movements

(57) A system is disclosed for selection of orthotics elements suitable for a person in need of such orthotic elements, the system comprising:

a set of a plurality of pre-designed orthotic elements 6;
a knowledge database 2 storing linked data structures, the linked data structures recording associations relating to a plurality of combinations of individual orthotics elements comprised in the set 6, each association being between measured characteristics 4 of the body element for which the combination was found suitable and the combination itself;

input means 4 for inputting a description of characteristics of a body element for which a combination of orthotic elements is to be determined; and

a decision means 3 for deciding on a combination of individual orthotic elements comprised in said set using the knowledge database.

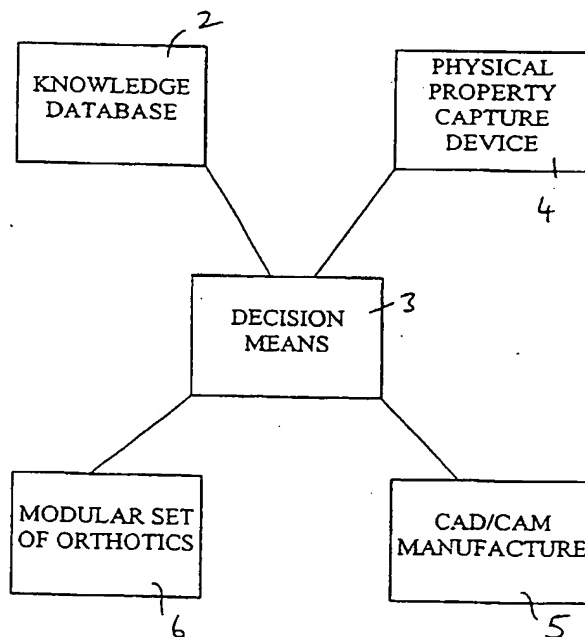


Fig. 1

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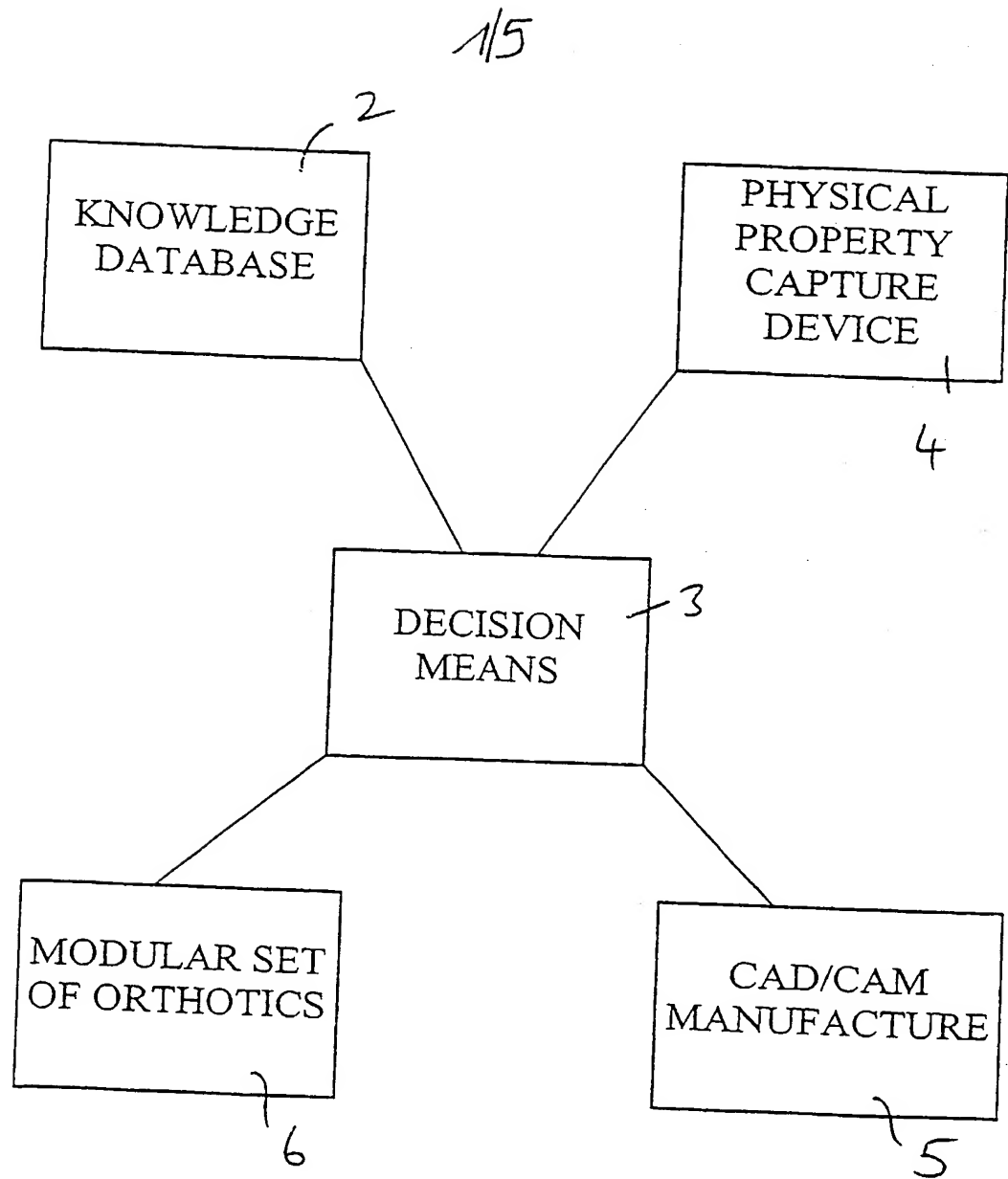


Fig. 1

2/5

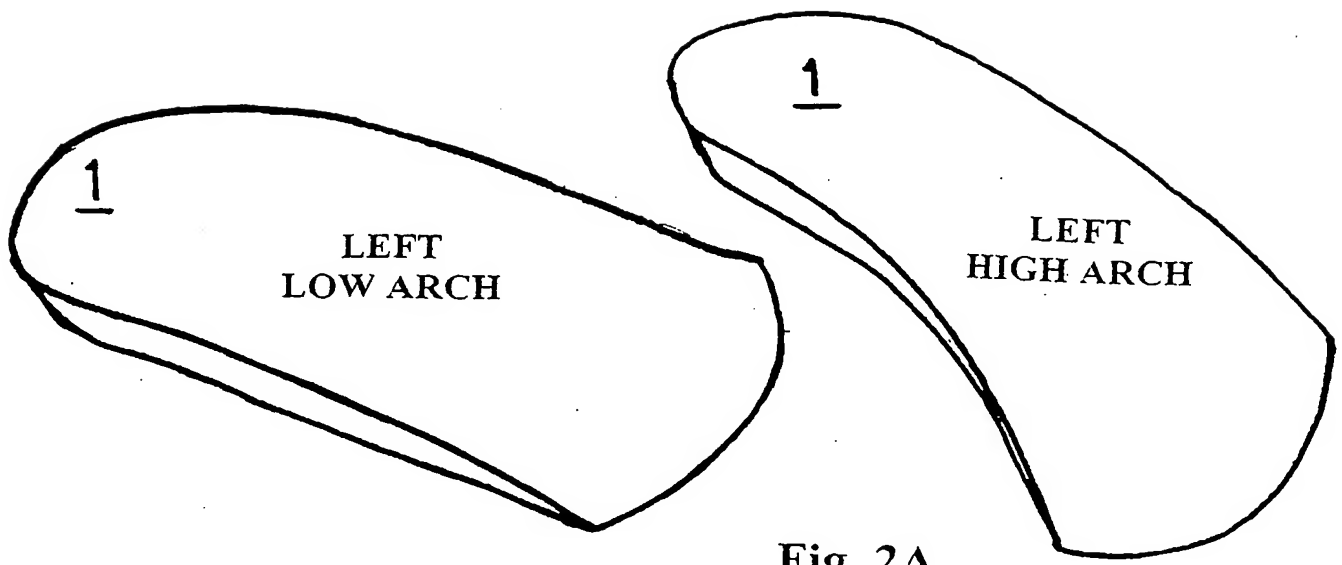
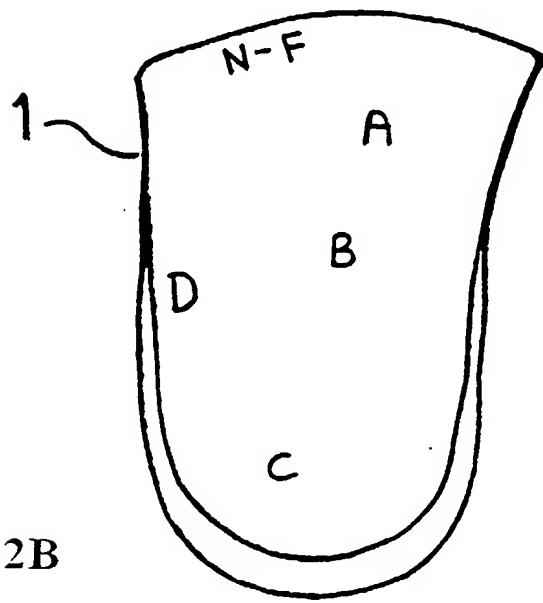


Fig. 2A



RIGHT

Fig. 2B

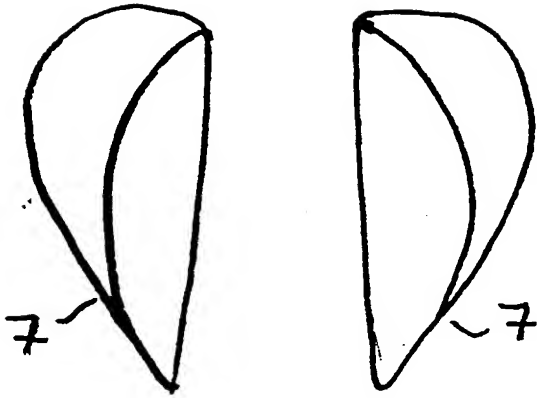
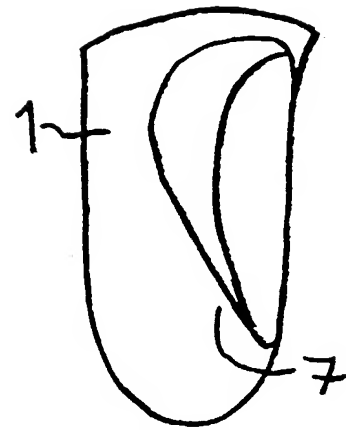


Fig. 3A



Right Foot

Fig. 3B

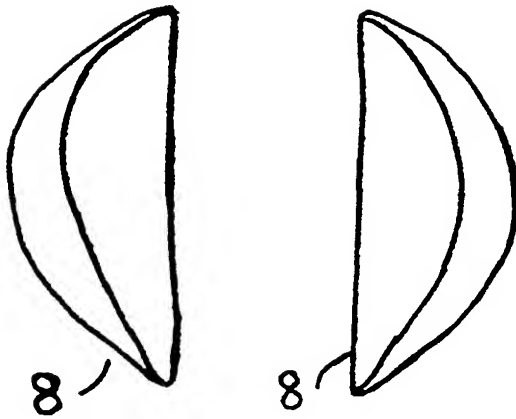
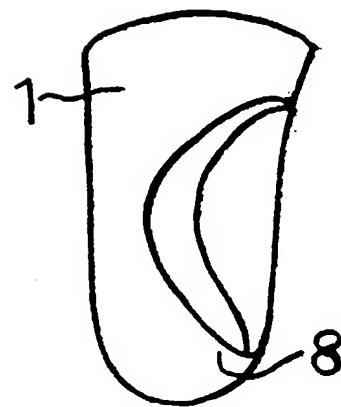


Fig. 3C

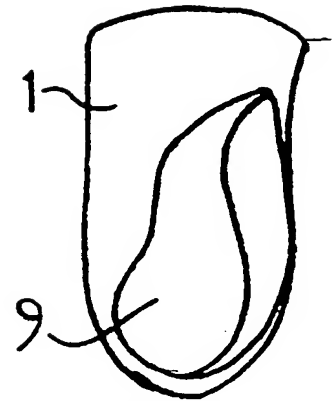
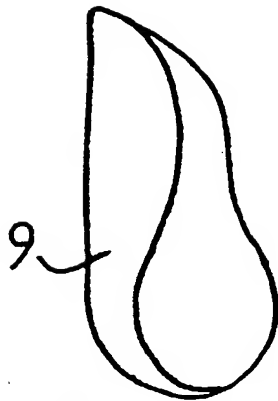


Right Foot

Fig. 3D



Fig. 3E

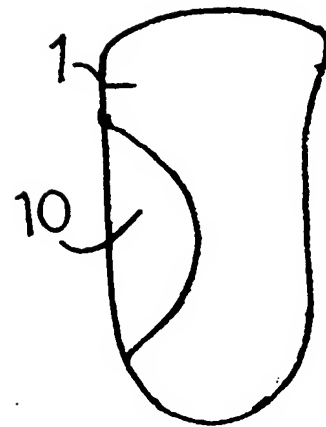


Right Foot

Fig. 3F



Fig. 3G



Right Foot

Fig. 3H

515

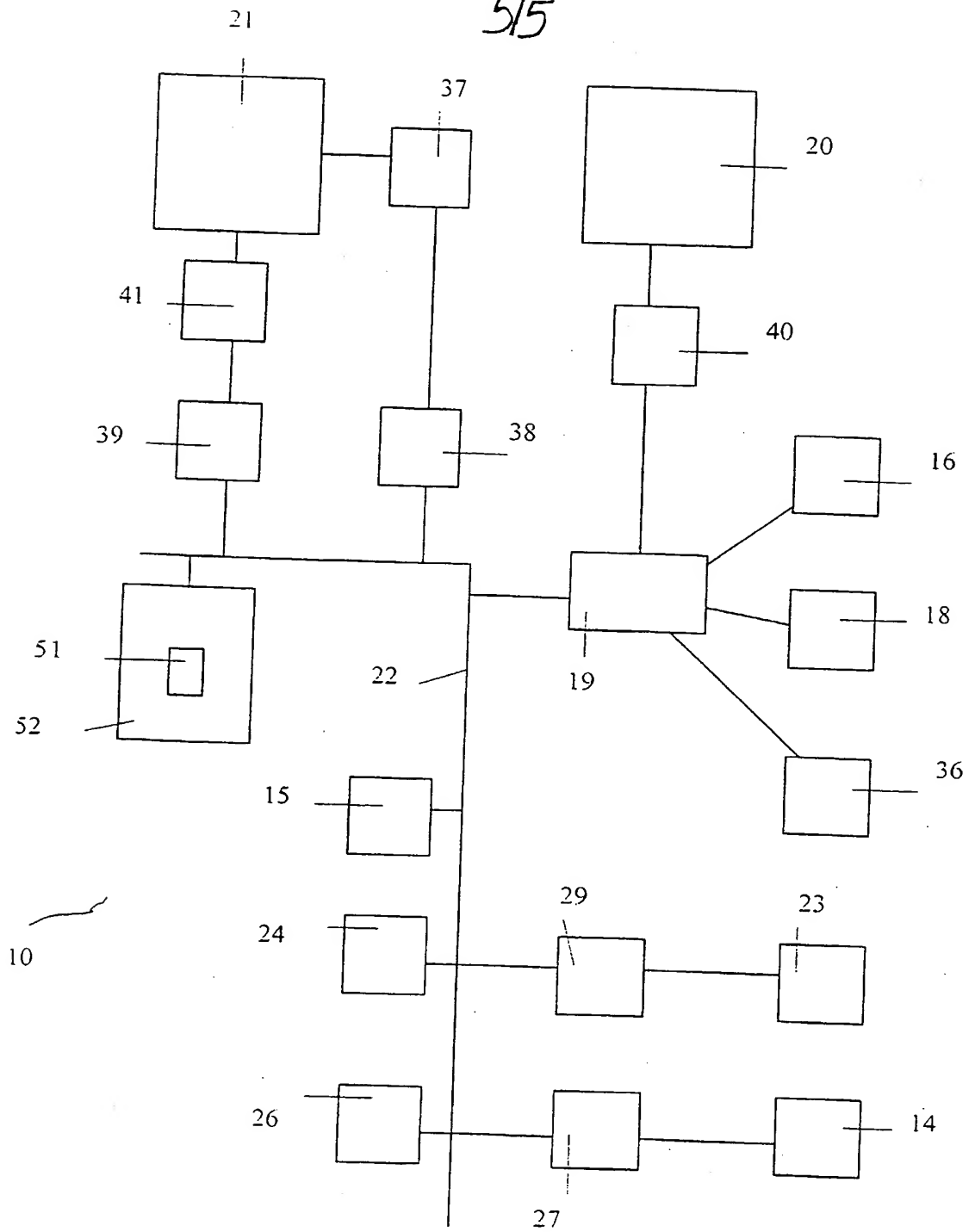


Fig. 4

**METHOD AND APPARATUS FOR OBTAINING NEUTRAL FOOT
POSITION AND CORRECTION OF PATHOLOGICAL FOOT MOVEMENTS**

FIELD OF THE INVENTION

- 5 The present invention relates to methods and apparatus for the obtaining of neutral foot position and correction of pathological foot movements in humans or other animals.

TECHNOLOGICAL BACKGROUND

- 10 US 5,058,585 describes an orthotic shoe insert comprising a unitary curved wedge having a heel portion, a middle portion to engage the plantar side of the medial portion of the longitudinal arch of the human foot and a front portion adapted to engage the plantar side just distal of the first and second metatarsal heads.

- 15 US 4,747,410 discloses an orthotic insert of unitary construction formed from a compressible plastic, and featuring an anterior varus wedge, a medial shelf and a heel cup.

- US 4,628,936 describes a segmented foot orthosis comprising a heel segment and a medial and a lateral longitudinal foot segment.

- 20 In can be generally stated that several known methods of correcting foot or gait defects rely on a degree of trial and error and very often the intervention of or control by experienced doctors. This requires sufferers of foot or gait problems to travel to specialist clinics to obtain expert advice, to wear provisional foot wear for some time and go through an iterative procedure of wearing modified provisional footwear before
25 suitably corrective and comfortable footwear is obtained.

- One object of the present invention is the provision of apparatus and methods which make selection of orthotics easier and more reliable. Another object of the present
30 invention is the provision of apparatus and methods which allow selection of orthotics by non-medically trained shop personnel.

SUMMARY OF THE PRESENT INVENTION

The present invention provides a system for selection of orthotic elements suitable for a person in need of such orthotic elements, comprising:

- a set of a plurality of pre-designed orthotic elements;
- a knowledge database storing linked data structures; the linked data structures
- 5 recording associations relating to a plurality of combinations of individual orthotics elements comprised in the set, each association being between measured characteristics of the body element for which the combination was found suitable and the combination itself;
- input means for inputting a description of characteristics of a body element for
- 10 which a combination of orthotic elements is to be determined; and
- a decision means for deciding on a combination of individual orthotic elements comprised in said set using the knowledge database.

The system may also include means to capture the characteristics of the body element.

15 For example, the body element may be a foot, and the capture means may be a pressure plate for measuring a pressure distribution of the foot during walking.

The system may also include means to carry out statistical analysis of the knowledge database to find an optimised fit between the plurality of stored combinations of

20 orthotic elements and characteristics and the characteristics of a new body element.

The present invention may also provide a method for selection of orthotic elements suitable for a person in need of such orthotic elements, comprising the steps of:

- providing a set of a plurality of pre-designed orthotic elements;
- 25 storing in a knowledge database linked data structures; the linked data structures recording associations relating to a plurality of combinations of individual orthotic elements comprised in the set, each association being between measured characteristics of the body element for which the combination was found suitable and the combination itself;
- 30 inputting a description of characteristics of a body element for which a combination of orthotic elements is to be determined; and
- deciding on a combination of individual orthotic elements comprised in said set using the knowledge database.

The method may also include capturing the characteristics of the body element to be fitted with the orthotics. For example, the body element may be a foot, and the capture may include use of a pressure plate for measuring a pressure distribution of the foot during walking.

The method may also include carrying out statistical analysis of the knowledge database to find an optimised fit between the plurality of stored combinations and characteristics and the characteristics of a new body element.

10

The present invention also includes a computer system particularly prepared or a computer program product to execute any of the methods of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

15 The present invention will now be described by way of example only and with reference to the accompanying drawings, in which:

Figure 1 shows schematically an orthosis selection system in accordance with an embodiment of the present invention;

20

Figures 2A and 2B show a basic insert for a shoe in accordance with an embodiment of the present invention, Figure 2A showing a top view and Figure 2B a bottom view;

Figure 3A shows a medial arch support with extension under the First Shaft in accordance with an embodiment of the present invention;

25

Figure 3B shows how the wedge/arch of Figure 3A is located on the basic insert of Figures 2A and 2B;

30 Figure 3C shows a raised medial foot arch support in accordance with an embodiment of the present invention;

Figure 3D shows how the element of Figure 3C is located on the basic insert of Figures

2A and 2B;

Figure 3E shows a rear foot anti-pronation element or rear foot supinator in accordance with an embodiment of the present invention;

5

Figure 3F shows how the element of Figure 3E is located on the basic insert of Figures 2A and 2B;

Figure 3G shows an anti-supination element or lateral stabiliser in accordance with an
10 embodiment of the present invention; and

Figure 3H shows how the element of Figure 3G is located on the basic insert of Figures 2A and 2B.

15 Figure 4 shows a computer system with which the present invention may be used.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The present invention will be described with respect to certain embodiments and drawings but is not limited thereby or thereto but only by the claims. In the
20 following, the invention will mainly be described with reference to orthotics for foot or gait defects but the present invention is not limited thereto but may be used advantageously with any orthotics for animals or humans for other body elements different from feet.

25 Figure 1 is a schematic representation of a system in accordance with an embodiment of the present invention for selecting orthotics. The system comprises a knowledge database 2, a decision means 3 and a physical property capture device 4. Optionally, the system may be in communication or may provide design specifications to a CAD/CAM manufacturing facility 5. In addition there is a set 6 of pre-defined
30 orthotic elements preferably designed using a modular approach, i.e. a set of pre-defined orthotic elements which can be combined in a modular manner to provide differing combinations of the elements to meet different patient needs. In the following the description will be continued based on a system for selecting orthotics for foot and

gait defects in humans but this is only an example of the invention used to illustrate the invention and to describe only one of the many ways it may be implemented.

As shown in Figure 2 a basic insert 1 for a shoe is provided made of a suitable material such as a foam rubber or plastic such as ethyl vinyl acetate (EVA) or any other suitable support material such as cork. The stiffness or hardness of the insert should be chosen to be compatible with the forces and loads placed upon it. A Shore hardness in the range of 40 to 70 has been found to be suitable. For foamed EVA a Shore hardness of 50 and for cork a Shore hardness of 60 has been found suitable.

10

The basic insert 1 may be provided in a set of different sizes to suit persons of different ages and foot size. Also the thickness and shape of the basic insert 1 may be varied to provide for different foot arch shapes. Typically, four basic forms of basic insert 1 are provided: one for high and one for low arch support in left foot and right versions, respectively. Starting from these basic forms a selection of different sizes for each form are made to deal with different foot sizes. Figure 2A shows a top view and Figure 2B shows a bottom view of the basic insert 1.

As shown in Figures 3A, 3B; 3C, 3D; 3E, 3F; 3G, 3H a set of at least four orthotic insert elements for shoes are pre-defined, i.e. are provided in a modular form. These may include:

As shown schematically in Figure 3A, a medial arch support with extension under the First Shaft comprising a forefoot anti-pronation wedge 7 for supporting and/or unloading of the First Shaft and to decrease excessive pressure loads under joints from metatarsal 1 and 2 in order to correct excessive and/or sustained pronation. How this wedge is located on the basic insert 1 is shown in Figure 3B.

As shown schematically in Figure 3C, a raised medial foot arch support comprising a mid-foot anti-pronation element 8 for medial foot arch correction and support, to prevent drop down of a hypermobile medial foot arch, to restrict and accompany an excessive medial mobility of the midtarsal joint and to give direct support under the sustentaculum hence aiming for a neutral position in the subtalar joint during motion.

How this element is located on the basic insert 1 is shown in Figure 3D.

As shown schematically in Figure 3E, a rear foot anti-pronation element or rear foot supinator 9, to provide a varus correction element providing direct support under the sustentaculum, to prevent drop down of a hypermobile medial foot arch and to restrict and accompany an excessive medial mobility of the midtarsal joint, hence aiming for a neutral position in the subtalar joint during motion. How this element is located on the basic insert 1 is shown in Figure 3F.

As shown schematically in Figure 3G, an anti-supination element or lateral stabiliser 10 to provide a valgus correction element under the calcaneus with lateral foot shaft support, to strengthen the lateral border of the orthosis, to restrict the varusation during motion and lateral drop down during inversion of the calcaneus and to increase the function of the "high" medial elements and to prevent supination. How this element is located on the basic insert 1 is shown in Figure 3H.

Further orthotic elements may be pre-defined by combinations of any of the above elements. For instance a fifth orthotic element may be created out of a combination of the forefoot anti-pronation wedge 7 and the rear foot anti-pronation element 9 to provide a medial arch support with extension under the First Shaft having a varus correction element under the calcaneus and a medial support element to provide medial arch support with extension under the First Shaft to decrease excessive pressure under the joints from metatarsal 1 and 2 and to prevent excessive and/or sustained pronation. Such a new combination of the modular orthotic elements provide a new orthotic element in the set and may prevent drop down of a hypermobile medial foot arch, restrict and accompany an excessive medial mobility of the midtarsal joint and give direct support under the sustentaculum, hence aiming for a neutral position in the subtalar joint during motion.

All the orthotic elements shown in Figure 3 may be made of a suitable material such as a foam rubber or plastic such as ethyl vinyl acetate (EVA) or any other suitable support material such as cork. The stiffness or hardness of the insert should be chosen to be compatible with the forces and loads placed upon it. A Shore hardness in the range of

40 to 70 has been found to be suitable. For foamed EVA a Shore hardness of 50 and for cork a Shore hardness of 60 has been found suitable. each orthotic insert element may be provided in a set of different sizes to suit persons of different ages and foot size. Also the thickness and shape of the basic insert 1 may be varied to provide for
 5 different foot shapes. Typically, two basic forms of each orthotic insert element are provided: one for left and one for right feet, respectively. Starting from these basic forms a selection of different sizes for each form are made to deal with different foot sizes.

10 The physical property capture device 4 may typically be a commercially available foot scanning system as marketed under the trade name Footscan™ by Rsscan International, Belgium. Such scanning systems are described, for instance, in European patent applications: EP 00200568.4 "A Method an Apparatus for determining a flexural property of a load applied to a discretely sampled pressure sensor array" and
 15 EP 0970657 (EP 98202334.3) "Apparatus and Method for measuring the pressure distribution generated by a three dimensional object" which are incorporated herein by reference. Such devices produce an output detailing various aspects of the pressure distribution of a human foot when the person is stationary and/or moving, e.g. walking and/or running. Further, from the pressure distribution other factors may be derived by
 20 calculation, e.g. the instantaneous principal bending axes of the leg/foot of the patient, the instantaneous angle of the principle bending axes, the instantaneous radius of gyration of the foot of the patient, instantaneous sheer forces between the foot and the foot scanning device, the directions of the sheer stresses, etc. This output is provided to the decision means 3. Decision means 3 may be implemented as a dedicated intelligent
 25 device or may be a general purpose computer provided with the appropriate software for running a decision program thereon.

The knowledge database 2 preferably provides the results of fitting the set of orthotic elements described with respect to Figures 2 and 3 to a large variety of persons with
 30 different foot or gait problems. The database 2 records the combined knowledge available relating to the successful application of the above orthotic inserts and elements as a data structure which links this data to the corresponding outputs of the physical property capture device 4. These data structures may be in the form of linked

tables, one table giving the selected combination of orthotic elements and the other table giving a physical description of the results of measuring the patients foot and gait on the physical property capture device 4. Preferably, knowledge database 2 includes the results of the selection of a large number of orthotic combinations, e.g. 25,000 different feet and/or gaits.

Device 4 may make use of the knowledge database 2 in the following way. A new patient is measured using the physical property capture device 4, e.g. foot pressure distributions are measured using a foot scanner and the relevant physical properties of the foot are derived therefrom, e.g. automatically. These results are output to the decision means 3. Based on this data, the decision means 3 builds an enquiry for the knowledge database 2. The purpose of this enquiry is to determine which records in the database 2 are the same as or most similar to the new data. Various algorithms may be used to make a probabilistic selection of the closest existing data in the database 2 as known to the skilled person. The result of the enquiry is the automatic selected of a combination of orthotic elements described above for the patient concerned. Once this combination is known a shop assistant may select a basic insert 1 (Figure 2) and orthotic elements (Figure 3) from pre-manufactured stock. Alternatively, the design details for the combination may be provided to a CAD/CAM manufacturing facility 5 and the basic insert 1 and the orthotic elements manufactured directly.

Once a suitable basic insert 1 and a combination of one or more orthotic elements 7-10 have been selected the shop assistant may glue these together preferably using pre-marked reference lines on the base of the basic insert 1 to produce the final orthosis for insertion in the shoe (s) of the patient.

Once a combination has been selected an applied as described above, the new result may be recorded in the database 2.

Fig. 4 is a schematic representation of a computing system which can be utilized with the methods and in a system according to the present invention. A computer 10 is depicted which may include a video display terminal 14, a data input means such as a keyboard 16, and a graphic user interface indicating means such as a mouse 18.

Computer 10 may be implemented as a general purpose computer, e.g. a Personal Computer or UNIX workstation.

Computer 10 includes a Central Processing Unit ("CPU") 15, such as a conventional
5 microprocessor of which a Pentium III processor supplied by Intel Corp. USA is only
an example, and a number of other units interconnected via system bus 22. The
computer 10 includes at least one memory. Memory may include any of a variety of
data storage devices known to the skilled person such as random-access memory
("RAM"), read-only memory ("ROM"), non-volatile read/write memory such as a hard
10 disc as known to the skilled person. For example, computer 10 may further include
random-access memory ("RAM") 24, read-only memory ("ROM") 26, as well as an
optional display adapter 27 for connecting system bus 22 to an optional video display
terminal 14, and an optional input/output (I/O) adapter 29 for connecting peripheral
devices (e.g., disk and tape drives 23) to system bus 22. Video display terminal 14 can
15 be the visual output of computer 10, which can be any suitable display device such as a
CRT-based video display well-known in the art of computer hardware. However, with
a portable or notebook-based computer, video display terminal 14 can be replaced with
a LCD-based or a gas plasma-based flat-panel display. Computer 10 further includes
user interface adapter 19 for connecting a keyboard 16, mouse 18, optional speaker 36,
20 as well as allowing optional physical value inputs from physical value capture devices
such as sensors 40 of an external system 20. The sensors 40 may be any suitable
sensors for capturing physical parameters of a person's body or limbs, e.g. feet or gait,
e.g. pressure sensor arrays. These sensors may include any sensor for capturing
relevant physical values required for provision of orthotic elements. Additional or
25 alternative sensors 40 for capturing physical parameters of an individual for provision
of orthotic elements may also be connected to bus 22 via a communication adapter
connecting computer 10 to a data network such as the Internet, an Intranet a Local or
Wide Area network (LAN or WAN) or a CAN. This allows transmission of physical
values or a representation of the physical values over a telecommunications network,
30 e.g. entering a description of an individual's performance at a near location and
transmitting it to a remote location, e.g. via the Internet, where a processor carries out a
method in accordance with the present invention and returns a parameter relating to at
least one orthotic element at a near location.

The terms "physical value capture device" or "sensor" includes devices which provide values of parameters of suitable for the provision of orthotic elements. The present invention also includes within its scope that the relevant physical values are input
5 directly into the computer using the keyboard 16 or from storage devices such as 23.

A CAD/CAM manufacturing facility 21 may also be provided. A parameter control unit 37 of system 21 may also be connected via a communications adapter 38. Parameter control unit 37 may receive an output value from computer 10 running a
10 computer program for numerical analysis in accordance with the present invention or a value representing or derived from such an output value and may be adapted to alter a parameter of system 21 in response to receipt of the output value from computer 10. For example, the dimension of one or more orthotic elements may be altered based on the output, a material may be changed, e.g. from rubber to wood, or a material may be
15 modified, e.g. a different hardness of rubber based on the output.

Computer 10 also includes a graphical user interface that resides within machine-readable media to direct the operation of computer 10. Any suitable machine-readable media may retain the graphical user interface, such as a random access memory (RAM)
20 24, a read-only memory (ROM) 26, a magnetic diskette, magnetic tape, or optical disk (the last three being located in disk and tape drives 23). Any suitable operating system and associated graphical user interface (e.g., Microsoft Windows) may direct CPU 15. In addition, computer 10 includes a control program 51 which resides within computer memory storage 52 or on other memory storage devices such as a hard disk. Control
25 program 51 resident on storage 52 contains instructions that when executed on CPU 15 carry out the operations described with respect to any of the methods of the present invention.

In particular a knowledge database storing linked data structures may be stored on
30 computer 10. The linked data structures record associations relating to a plurality of combinations of individual orthotic elements comprised in a set, each association being between measured characteristics of a body element for which the combination was

found suitable and the combination itself.

Software running on computer 10 also provide a decision means for deciding on a combination of individual orthotic elements comprised in said set using the knowledge database.

Those skilled in the art will appreciate that the hardware represented in Fig. 4 may vary for specific applications. For example, other peripheral devices such as optical disk media, audio adapters, or programming devices, such as PAL or EPROM programming devices well-known in the art of computer hardware, and the like may be utilized in addition to or in place of the hardware already described.

In the example depicted in Fig. 4, the computer program product (i.e. control program 51) can reside in computer storage. However, it is important that those skilled in the art will appreciate that the mechanisms of the present invention are capable of being distributed as a program product in a variety of forms, and that the present invention applies equally regardless of the particular type of signal bearing media used to actually carry out the distribution. Examples of computer readable signal bearing media include: recordable type media such as floppy disks and CD ROMs and transmission type media such as digital and analogue communication links.

While the invention has been shown and described with reference to preferred embodiments, it will be understood by those skilled in the art that various changes or modifications in form and detail may be made without departing from the scope and spirit of this invention as defined in the attached claims.

For example, different orthotic elements may be used with the present invention. For instance, they may comprise whole shoe designs rather than discrete elements. Hence, they may be design elements of a complete shoe design which are then used to manufacture the final shoe. Hence, the word "orthotic element" should be given its broadest meaning including both a physical element such as a wedge as well as a design element of a larger orthosis.

For instance, the present invention may be used with other body elements than feet. Also other scanning devices may be used. It is only required that the physical value capture devices 4 are able to capture values of physical properties which may be used
5 to select the appropriate combination of orthotic elements.

Claims

- 1) A system for selection of orthotic elements suitable for a person in need of such orthotic elements, comprising:
 - 5 a set of a plurality of pre-designed orthotic elements;
 - a knowledge database storing linked data structures, the linked data structures recording associations relating to a plurality of combinations of individual orthotics elements comprised in the set, each association being between measured
 - 10 characteristics of the body element for which the combination was found suitable and the combination itself;
 - input means for inputting a description of characteristics of a body element for which a combination of orthotic elements is to be determined; and
 - 15 a decision means for deciding on a combination of individual orthotic elements comprised in said set using the knowledge database.
- 2) A system according to claim 1, further including means to capture the
 - 20 characteristics of the body element.
- 3) A system according to claim 2, wherein the body element comprises a foot and the capture means comprises a pressure plate for measuring a pressure distribution of the foot during walking.
- 4) A system according to any preceding claim, further including means to carry out
 - 25 statistical analysis of the knowledge database to find an optimised fit between the plurality of stored combinations of orthotic elements and characteristics and the characteristics of a new body element.
- 5) A system for selection of orthotic elements substantially as described herein and with reference to the accompanying drawings.
- 30 6) A method for selection of orthotic elements suitable for a person in need of such orthotic elements, comprising the steps of:

- providing a set of a plurality of pre-designed orthotic elements;
- storing in a knowledge database linked data structures, the linked data structures
5 recording associations relating to a plurality of combinations of individual orthotic
elements comprised in the set, each association being between measured
characteristics of the body element for which the combination was found suitable
and the combination itself;
- 10 inputting a description of characteristics of a body element for which a
combination of orthotic elements is to be determined; and
- deciding on a combination of individual orthotic elements comprised in said set
using the knowledge database.
- 15 7) A method according to claim 6, including capturing the characteristics of the body
element to be fitted with the orthotics.
- 8) A method according to claim 7, the body element comprising a foot, and the
capture including using a pressure plate for measuring a pressure distribution of the
20 foot during walking.
- 9) A method according to any one of claims 6 to 8, including carrying out a statistical
analysis of the knowledge database to find an optimised fit between the plurality of
stored combinations and characteristics and the characteristics of a new body
25 element.
- 10) A method for selection of orthotic elements substantially as described herein and
with reference to the accompanying drawings.

- 11) A program storage device, storing instructions that when executed by a computer system having a memory perform any of the methods of any of claims 6 to 10.
- 5 12) A computer program product for executing any of the methods of any of claims 6 to 10 when executed on a computing device.
- 10 13) Linked data structures stored in a memory, the linked data structures storing associations relating to a plurality of combinations of individual orthotic elements comprised in a set, each association being between measured characteristics of a body element for which the combination was found suitable as for orthotic purposes and the combination itself.
- 14) A computer system particularly prepared to execute any of the methods of any of claims 6 to 10.



INVESTOR IN PEOPLE

Application No: GB 0126912.5
Claims searched: 1 - 14

Examiner: Tom Sutherland
Date of search: 26 April 2002

Patents Act 1977 Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:
UK CI (Ed.T):
Int CI (Ed.7): A61F 5/14; A61B 5/103, 5/107; A43B 7/14, 7/16, 7/20
Other: Online: WPI, EPODOC, JAPIO

Documents considered to be relevant:

Category	Identity of document and relevant passage	Relevant to claims
X	WO 97/15250 A (PENINSULA PODIATRIC) Whole document.	1 - 14
X	US 5746952 (MARSHALL) Whole document.	1 - 14

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